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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,790	06/06/2006	Martina Kotthaus	4662188	5491
<div>23117      7590      08/14/2007</div> <div>NIXON &amp; VANDERHYE, PC</div> <div>901 NORTH GLEBE ROAD, 11TH FLOOR</div> <div>ARLINGTON, VA 22203</div>				
			EXAMINER NAGUBANDI, LALITHA	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 08/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/581,790	Applicant(s) KOTTHAUS ET AL.	
	Examiner Lalitha Nagubandi	Art Unit 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/6/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

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***Detailed Office Action***

***Status of Claims***

Claims 1-9 are pending. Claims 1-9 are considered for examination in this office action.

***Priority***

This application is a 371 of PCT/EP04/12919 dated 11/15/2004, and claims priority to Austria A No. 1968/2003 dt. 12/09/2003. Applicants cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware, in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 1 – 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claim 1, step (d) line 3, formula (VI\*) has been used. Examiner does not find formula (VI\*) either in the specification or in the claims.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. Chiral amide of the formula (VI\*) is critical or essential to the practice of the invention, but not included in the claim(s) and is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

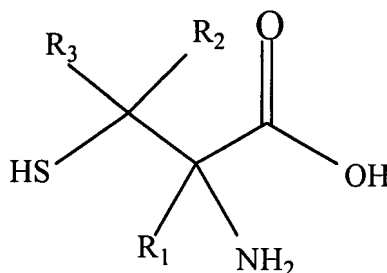
1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higuchi et al (WO 2004/090152 A1 which is now US Pat No. 7,207,631 B2) and in view of Kondo et al (US Pat No. 6,011,170 dt. Jan. 4, 2000).

Applicants' claim a process for preparing chiral mercapto amino acids of the formula



(I)

in which the  $R_1$ ,  $R_2$  and  $R_3$  are as embodied. The process is characterized of the following steps

(a) an oxo compound of the formula (II) is reacted in the presence of ammonia or ammonium hydroxide and of a sulfide from the group of ammonium hydroxide and of a sulfide from the group of ammonium hydrosulfide, alkaline earth metal hydrosulfides or alkali metal hydrosulfides with phase transfer catalysis or with addition of a solubilizer, with a ketone or aldehyde of the formula (III) to give the compound of the formula (IV).

(b) reacts with HCN to give the compound of the formula (V)

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( c ) the crystallized compound of the formula (V) is converted by selective hydrolysis using a mineral acid to the corresponding amide of the formula (VI).

(d) Compound of formula (VI) is converted to compound of formula (VI\*) a chiral amide using an amidase or a chiral resolving acid.

Note: (formula VI\* not embodied in the claims)

(e) The desired chiral mercapto amino acid of the formula (I) is obtained by reaction with an acid of the chiral amide.

The process further characterized step (d) or (e) an L-amidase prepared from Mycobacterium smegmatis ATCC 25795, Mycobacterium smegmatis ATCC 19420 or Mycoplasma dimorpha IFO 13291 or a chiral resolving acid from the group of tartaric acid etc.

#### **Determination of Scope and content of the Prior Art (MPEP§2141.01)**

Higuchi et al teach (col. 5 lines 5- 25 and col. 6 and lines 5- 65 and please see claims 2 and 4), process for producing chiral 2-alkyl cysteinamide and also 2-alkyl-cysteine.

Kondo et al teach ( See abstract and col. 9 and 10 ,Table 1) teach the reaction of amino acid derivatives to give cysteine derivative in presence phase transfer catalysis.

#### **Ascertainment of the difference between the Prior Art and Claims (MPEP §2141.02)**

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The difference between the instant process and Higuchi et al is that the instant process requires a phase transfer catalyst for the replacement of the halogen and Higuchi is silent about the use of phase transfer catalyst during the halogen replacement reaction.

Kondo teaches a reaction where X is a leaving group and is replaced by a thiol resulting in a cysteine derivative under phase transfer catalysis conditions.

**Finding of prima facie obviousness – rational and motivation (MPEP § 2142-2143)**

It would have been obvious to use a phase transfer catalyst during the halogen replacement process in the invention of Higuchi, because a skilled artisan would be motivated to choose alternative catalysts and ambient experimental conditions.

Therefore the subject matter as a whole would have been obvious to one of ordinary skill in the art of process chemistry and one would have been motivated to combine and modify the teachings cited above at the time of the invention and obtain a reasonable expectation of success.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996.

The examiner can normally be reached on 6.30am to 3.30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

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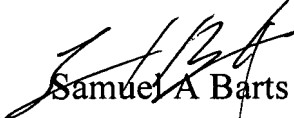
Eyler, Yvonne can be reached on 571 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lalitha Nagubandi

Patent Examiner  
Technology Center 1600

August 9th, 2007.



Samuel A Barts

Primary Patent Examiner  
Technology Center 1600

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